REMARKS

Claims 1 through 17 are pending in this Application. Claims 1, 6, and 11 have been amended, and new claims 16 and 17 have been added. In addition the specification has been amended at the request of the Examiner. Care has been exercised to avoid the introduction of new matter. Adequate descriptive support for the present Amendment should be apparent throughout the originally filed disclosure as, for example, paragraph [0010] of the written description of the specification with respect to the amendments to claims 1 and 6, and paragraphs [0010], [0032], [0047], and [0049], as well as Fig 3, with respect to new claims 16 and 17. Formalistic changes have also been made to claims 6 and 11 at the suggestion of the Examiner. Applicants submit that the present Amendment does not generate any new matter issue.

Objection to the Specification.

The Examiner objected to the Specification, asserting that the previous Amendment introduced new matter into paragraph [0024].

In response, paragraph [0024] has been amended to that originally filed, thereby overcoming the stated basis for the objection. Accordingly, withdrawal of the objection to the specification is solicited.

Claim Objections.

The Examiner objected to claims 6 and 11, identifying formalistic issues and courteously suggesting appropriate language. In response, claims 6 and 11 have been amended as suggested by the Examiner, thereby overcoming the stated bases for the claim objections. Accordingly, withdrawal of the objection to claims 6 and 11 is solicited.

Claims 1, 2, 6 through 8, and 10 were rejected under 35 U.S.C. §102(b) for lack of novelty based on Amano et al. as evidenced by Newsome et al.

In the statement of the rejection, the Examiner asserted that Amano et al. disclose a laminate and method identically corresponding to those claimed. This rejection is traversed.

The factual determination of lack of novelty under 35 U.S.C. §102(b) requires the identical disclosure in a single reference of each element of a claimed invention, as those elements are set forth in the claims, such that the claimed invention is placed into the recognized possession of one having ordinary skill in the art. *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1308, (Fed. Cir. 2008); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003); *Crown Operations International Ltd. v. Solutia Inc.*, 289 F.3d 1367 (Fed. Cir. 2002); *Candt Tech Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344 (Fed. Cir. 2001). Further, as a matter of procedural due process of law, the Examiner is required to specifically identify where in an applied reference is alleged to disclose each and every feature of a claimed invention, particularly when such is not apparent as in the present case. *In re Rijckaert, 9 F.3d 1531 (Fed. Cir. 1993); Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452 (Fed. Cir. 1984).* Moreover, there are fundamental differences between the claimed laminate and method and those disclosed by Amano et al. that scotch the factual determination that Amano et al. disclose, or even remotely suggest, a laminate and method identically corresponding to those claimed.

Specifically, independent claims 1 and 6 have been clarified by specifying that the transparent type I collagen sheet has a thickness ranging from 5 to 50 micrometers. Amano et al. neither disclose nor suggest a laminate or method of manufacturing a laminate comprising a transparent type I collagen sheet having a thickness ranging from 5 to 50 micrometers.

The above argued difference between the claimed inventions and Amano et al. is functionally significant. This is because the laminate of the present invention is used for transplantation by insertion into the anterior chamber, as described in the originally filed specification as well as encompassed by new claims 16 and 17. In order to successfully insert the laminate into the anterior chamber the base of the laminate must be thin enough to enable the laminate to be inserted into the anterior chamber. Therefore, a transparent type I collagen sheet ranging from 5 to 50 micrometers in thickness is used in the present invention. The inserted laminate is then fixed to the posterior corneal stroma.

In the method disclosed by Amano et al., the removed cornea is reconstructed by a method using cultured HCECs and corneal stroma, and then the reconstructed cornea is put back. The differences between the present method (anterior chamber insertion) and that of Amano et al. (whole corneal layers transplantation) are outlined below and further explained on the flow sheet attached hereto as Exhibit A.

Amano et al. (whole corneal layers transplantation): Upper

(a). Incision of the whole periphery of the cornea;

(b). Remove the incised cornea from an eye;

(c). Put the laminate of cultured HCECs and corneal stroma on posterior of the incised cornea to reconstruct the cornea;

(d). Return the reconstructed cornea to the eye; and

(e). Suture of the reconstructed cornea along the whole periphery.

The present invention (anterior chamber insertion): Lower

(x). Partial incision of the cornea;

(y). Insertion of the laminate with an injector (see the bottom of the picture) into the anterior chamber and fixing the laminate to the posterior of corneal stroma; and

(z). Partial suture of the cornea.

Although Amano et al. teach transplanting cultured HCECs in to the anterior chamber, Amano et al. fail to disclose or suggest inserting the laminate with a cultured HCECs layer on a thin transparent type I collagen sheet ranging from 5 to 50 micrometers.

There can be no doubt that the inventive method is manifestly superior to that of Amano et al. This is because in the present invention there is basically a small insertion into the anterior chamber. However, Amano et al. require an entire corneal layer transplant such that the patient goes without his or her cornea during the period when the cornea is reconstructed. In the present invention the patient does not undergo such inconvenience and exposure to danger. Moreover, in the present invention, the incision is much smaller in the anterior chamber insertion than in the procedure of Amano et al. wherein the entire corneal layers are transplanted. Significantly, in the inventive procedure, there is extremely little damage to the patient in the anterior chamber insertion and, therefore, more rapid recovery and a lower failure rate.

Moreover, there is no apparent basis upon which to conclude that one having ordinary skill in the art would have been realistically led by Amano et al. to prepare a laminate with a layer of cultured HCECs on a thin transparent type I collagen sheet ranging from 5 to 50 micrometers in thickness capable of being transplanted by anterior chamber insertion from Amano et al. *In re Kahn, 441 F.3d 977, 988 (C.A. Fed. 2006).*

The above argued functionally significant structural difference between the claimed laminate and method and those disclosed by Amano et al. undermine the factual determination that Amano et al. disclose a laminate and method identically corresponding to those claimed. *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics Inc.*, 976 F.2d 1559 (Fed. Cir. 1992); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565 (Fed. Cir. 1986). Applicants, therefore, submit that the imposed rejection of claims 1, 2, 6 through 8, and 10 under 35 U.S.C. §102(b) for lack of novelty based on Amano et al. as evidenced by Newsome et al. is not factually viable and, hence, solicit withdrawal thereof.

Claims 1 through 15 were rejected under 35 U.S.C. §103(a) for obviousness predicated upon Amano et al. in view of Civerchia, Miyata et al., and Inoue et al.

This rejection is traversed. Specifically, as previously argued, Amano et al. neither disclose nor suggest a laminate with a layer of cultured HCECs on a thin transparent type I collagen sheet ranging from 5 to 50 micrometers in thickness capable of being transplanted by anterior chamber insertion. Similarly, none of the secondary references discloses or suggest a laminate with a layer of cultured HCECs on a thin transparent type I collagen sheet ranging from 5 to 50 micrometers in thickness capable of being transplanted by anterior chamber insertion. Therefore, even if the applied references are combined as proposed by the Examiner, and Applicants do not agree that the requisite basis to support the asserted motivation has been established, the claimed invention would not result. *Uniroyal, Inc. v. Rudkin-Wiley Corp, 837 F.2d 1044 (Fed. Cir. 1988).*

Moreover, the above argued difference between the claimed inventions and the applied prior art is functionally significant. As previously argued, the use of a laminate with a layer of

cultured HCECs on a thin transparent type I collagen sheet ranging from 5 to 50 micrometers in thickness advantageously enables transplantation with an extremely small incision and hence, rapid recovery and lower failure.

Applicants therefore submit that the imposed rejection of claims 1 through 15 under 35 U.S.C. §103(a) for obviousness predicated upon Amano et al. in view of Civerchia, Miyata et al., and Inoue et al. is not factually or legally viable and, hence, solicit withdrawal thereof.

New claims 16 and 17.

New claims 16 and 17 are clearly free of the applied prior art for reasons which should be apparent from the arguments previously advanced. As previously argued, none of the applied references disclose or suggest a laminate with a layer of cultured HCECs on a thin transparent type I collagen sheet ranging from 5 to 50 micrometers in thickness capable of being transplanted by anterior chamber insertion as in the claimed invention. Accordingly, claims 16 and 17 are free of the applied prior art.

Based upon the foregoing, it is apparent that the imposed objections and rejections have been overcome, and that all pending claims are in condition for allowance. Favorable consideration is therefore solicited. If any unresolved issues remain, it is respectfully requested that the Examiner telephone the undersigned attorney at 703-519-9954 so that such issues may be resolved as expeditiously as possible.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 504213 and please credit any excess fees to such deposit account.

Respectfully Submitted,

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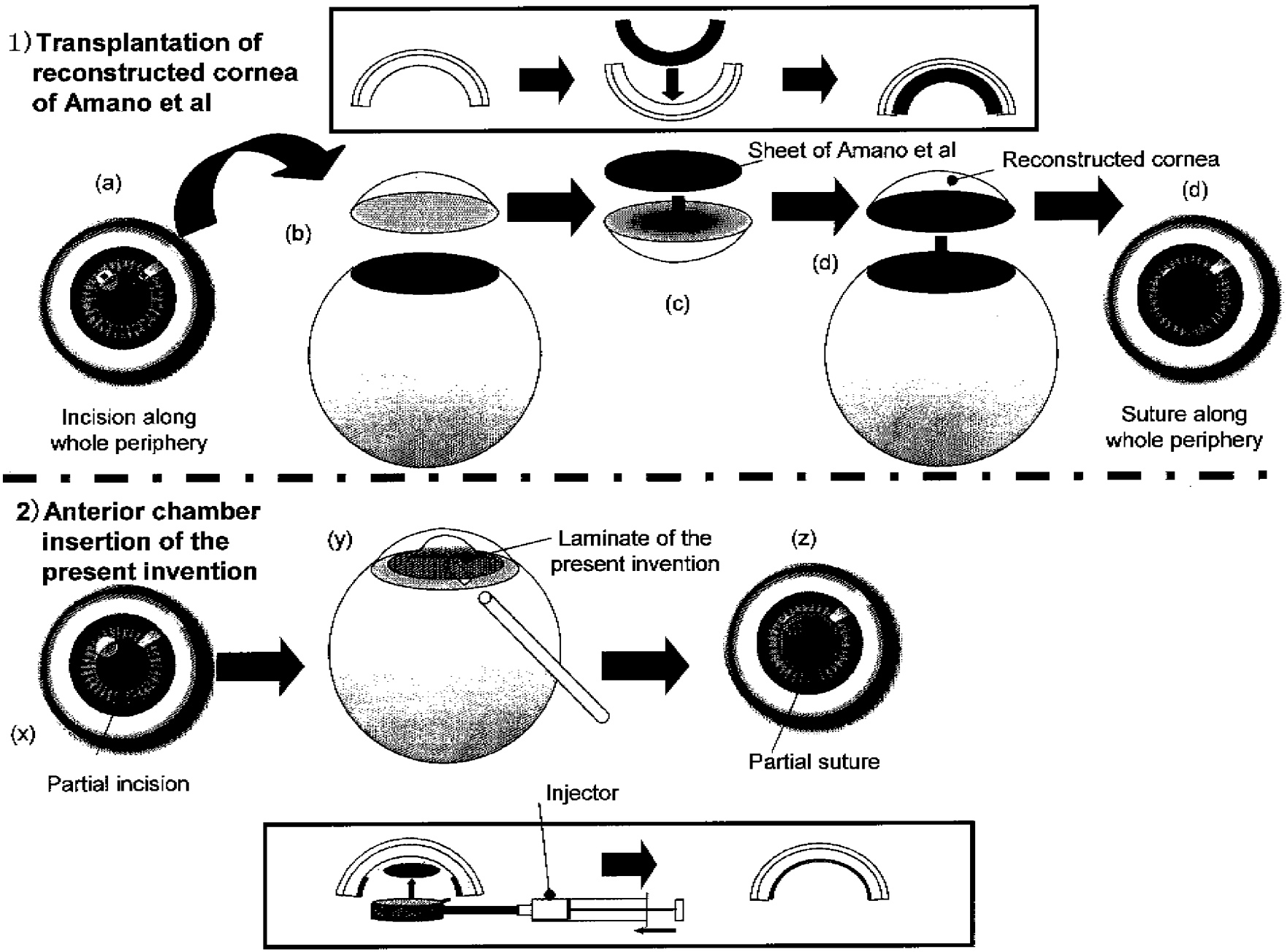
1) Transplantation of reconstructed cornea of Amano et al
(a)
(b)
(c)
(d)
(d)
Sheet of Amano et al
Reconstructed cornea
Incision along whole periphery
Suture along whole periphery
2) Anterior chamber insertion of the present invention
(x)
(y)
(z)
Laminate of the present invention
Partial incision
Partial suture
Injector

EXHIBIT A